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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,108	07/26/2001	Allyson Beuhler	CM01399I (9640/73)	7455

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,108	BEUHLER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

FINAL ACTION

1. This action is in response to papers filed 17 December 2002 in which claims 13-23 were canceled and claims 24-39 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 17 September 2003 are maintained as they apply to the previous rejections. Rejection not reiterated below are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are addressed as they apply to the instant rejections. New grounds for rejection necessitated by amendment are discussed.

Claims 24-39 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite for the recitation "the magnetic property" because the recitation lacks proper antecedent basis in Claim 24. It is suggested that Claim 33 be amended to provide proper antecedent basis.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 24-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al (U.S. Patent No. 5,869,748, issued 9 February 1999).

Regarding Claim 24, Stevenson et al disclose a biosensor comprising a substrate having at least one biodetection site (Fig. 1 and 4) and a resonator disposed on the biodetection site wherein the resonator measures at least one property of at least one untagged biomolecule at the biodetection site i.e. the resonator measures the conditions in each well during analysis e.g. increased mass, lack of growth corresponding to resonance (Column 8, lines 47-60 and Column 9, lines 22-36). It is noted that the recitation "the resonator measures at least one property of at least one untagged biomolecule at the biodetection site" is functional language. While Stevenson et al teach the functional language, it is the claimed structural components which define the invention.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claim 25, Stevenson et al disclose the biosensor further comprising at least one magnetic tag attachable to the biomolecule (Column 5, lines 61-Column 6, line 7).

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Regarding Claim 26, Stevenson et al disclose the biosensor wherein the substrate is glass i.e. glass disc (Column 8, lines 47-51).

Regarding Claim 27, Stevenson et al disclose the biosensor wherein the resonator is a radio frequency passive component (Column 8, lines 25-36).

Regarding Claim 28, Stevenson et al disclose the biosensor wherein the resonator comprises an inductor and capacitor (Column 8, lines 25-36).

Regarding Claim 29, Stevenson et al disclose the biosensor wherein the biomolecule is a protein i.e. antibody (Column 9, lines 5-16).

Regarding Claim 30, Stevenson et al disclose the biosensor wherein the biodetection site includes a holding substance i.e. glass disc (Column 8, lines 47-51 and 62-67).

Regarding Claim 31, Stevenson et al disclose the biosensor wherein the holding substance is a polymer i.e. glass is covered with cell binding material e.g. polylysine (Column 9, lines 31-34).

Regarding Claim 32, Stevenson et al disclose the biosensor wherein at least one biochemical probe is present at the biodetection site i.e. antibody (Column 9, lines 5-16).

Regarding Claim 33, Stevenson et al disclose the biosensor wherein a magnetic property "corresponds to" a value i.e. one ferritin particle labels one antibody (Column 5, lines 61-65) and the antibodies binding to their binding partner at the biodetection site thereby indicating a quantity of biomolecules at the detection site as claimed (Column 9, lines 5-16).

Regarding Claim 34, Stevenson et al disclose the biosensor further comprising a quantitator in communication with the biodetection site which determines the value i.e. detector connected to a PC (Column 8, lines 20-24).

Regarding Claim 35, Stevenson et al disclose the biosensor wherein the resonator has a spiral geometry i.e. coil (Column 8, lines 15-18).

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Regarding Claim 36, Stevenson et al disclose the biosensor further comprising a reader in communication with the biodetection site which analyzes data generated by the resonator i.e. detector connected to a PC (Column 8, lines 20-24 and 47-60).

Response to Arguments

6. Applicant has not provided arguments regarding the previous rejections under 35 U.S.C. 102(b) over Stevenson.

Applicant argues that Stevenson et al do not teach or suggest a biosensor having a resonator at the biodetection site which measures a resonance property of an untagged biomolecule. The argument has been considered but is not found persuasive because as stated above, the resonator of Stevenson et al measures the conditions in each well before and during analysis to determine increased mass, lack of growth corresponding to resonance (Column 8, lines 47-60 and Column 9, lines 22-36). They further teach that the resonance is measured regardless of whether a labeled probe is deposited on the surface (Column 8, lines 1-6). Therefore, they measure a property of an untagged cell.

Furthermore, the recitation "the resonator measures at least one property of at least one untagged biomolecule at the biodetection site" is functional language. While Stevenson et al teach the functional language, it is the claimed structural components which define the invention.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al (U.S. Patent No. 5,869,748, issued 9 February 1999) in view of Stratagene (catalog, 1988, page 39).

Regarding Claims 37-39, Stevenson et al teach a biosensor for assaying biomolecules comprising: a sample plate including a plurality of biodetection sites comprising a resonator; and a holding gel adapted to coat the biodetection site i.e. a cell-binding substance wherein the resonator allows measurement of magnetic properties at the biodetection sites (Claim 37); a solution of one biochemical probe adapted to be applied to the biodetection site (Claim 38); and solution of at least one magnetic tag adapted to be applied to the biomolecule (Claim 39) (Column 8, lines 47-60; Column 9, lines 5-37; Claims 1 and 16-18 and Fig. 4). Stevenson et al do not teach the sample plate, holding substance and electrical resonator combined into a kit. However, Stratagene catalog teaches a motivation to combine components into kit format (page 39).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the biosensor components of Stevenson et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

Response to Arguments

9. Applicant argues that Stevenson et al do not teach or suggest combining their biosensor into a kit format because their device comprises disposable components. The argument has been considered but is not found persuasive because as stated above, Stratagene provide the motivation to combine the reagents used in the biosensor into a kit format. Furthermore, the fact that Stevenson et al utilizes disposable components does not negate the fact that providing all of the reagents for bioanalysis into a kit format provides for convenience and quality control as taught by Stragene.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 1, 2003